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10/825,315	04/16/2004	Hirokazu Sakai	252003US0	7876

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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
DELCOTTO, GREGORY R	
ART UNIT	**PAPER NUMBER**
1796	

NOTIFICATION DATE	DELIVERY MODE
01/29/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.	Applicant(s)	
	10/825,315	SAKAI ET AL.	
	Examiner	Art Unit	
	Gregory R. Del Cotto	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,6 and 8* is/are pending in the application.

4a) Of the above claim(s) *8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4 and 6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 4, 6, and 8 are pending. Claims 2, 3, 5, and 7 have been canceled. Applicant's arguments and amendments filed 11/2/07 have been entered.

Claim 8 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/17/06.

Objections/Rejections Withdrawn

The following objections/rejections set forth in the Office action mailed 2/28/07 have been withdrawn:

The objection to claims 1, 4, and 6 because of informalities has been withdrawn.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO97/35548 in view of EP 1,166,766 and Hoshowski et al (US 5,137,715).

'548 teaches hair conditioning shampoo compositions containing a specific surfactant component comprising an ethoxylated alkyl sulfate surfactant having from about 1 to about 8 moles of ethoxylation and an amphoteric surfactant with insoluble, dispersed, nonionic silicone and a select soluble cellulosic cationic polymer hair conditioning agent. See Abstract. The alkyl ether sulfates contain an alkyl group of from about 8 to about 24 carbon atoms and have 1 to 8 moles of ethoxylated units. Highly preferred alkyl ether sulfates are those comprising a mixture of individual compounds, said mixture having an average alkyl chain length of from about 10 to about 16 carbon atoms and an average degree of ethoxylation of from about 1 to about 4 moles of ethylene oxide. See page 6, lines 1-22.

'548 does not teach the use of an amphiphatic amide lipid or a composition having the specific pH containing an amphiphatic amide lipid, a mixture of alkyl ether

sulfate surfactants, and the other requisite components of the composition in the specific amounts as recited by the instant claims.

'766 teaches dermatologic preparations capable of exerting excellent effects of maintaining normal barrier functions of the horny layer, restoring and reinforcing damaged barrier functions, heightening water retention of the horny layer and remedying skin chapping, and novel diamide derivatives having such effects. Suitable diamides include those having the same general formula as formula (1) of the instant claims. The cosmetics may be formulated into various forms such as W/O and O/W emulsion cosmetics such as hair cosmetics including hair conditioners, shampoos, etc. The amide may be used in amounts of 0.01 to 20% by weight. See page 6, lines 45-60. The hair cosmetic may contain surfactants such as anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants including alkyl ether sulfates, etc. These surfactants may be used in amounts from 5 to 30% by weight. See para. 24.

Hoshowski et al teach a hair shampoo-conditioner composition including an anionic cleansing surfactants, such as alkyl sulfate or an alkyl ether sulfate, and a polymeric conditioning compound, in a suitable carrier, and having a pH of from about 2.5 to less than 7, to cleanse the hair. See Abstract.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use an amphiphatic amide lipid in the composition taught by '548, with a reasonable expectation of success, because '766 teaches the

advantageous properties imparted to a similar shampoo composition when using an amphiphatic amide lipid.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to formulate the composition as taught by '548 at a pH as recited by the instant claims, with a reasonable expectation of success, because Hoshowski or teach formulating similar shampoo compositions at a pH which is the same as recited by the instant claims.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to formulate a composition having the specific pH containing an amphiphatic amide lipid, a mixture of alkyl ether sulfate surfactants, and the other requisite components of the composition in the specific amounts as recited by the instant claims, with a reasonable expectation of success and similar results with respect to other disclosed components, because the broad teachings of '548 in combination with '766 suggest a composition having the specific pH containing an amphiphatic amide lipid, a mixture of alkyl ether sulfate surfactants, and the other requisite components of the composition in the specific amounts as recited by the instant claims.

Claims 1, 4, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1,166,766 in view of WO97/35548 and Hoshowski et al (US 5,137,715),

'766 is relied upon as set forth above. However, '766 does not teach the use of a mixture of alkyl ether sulfates, a cationic cellulose polymer, or a composition having the specific pH containing an amphiphatic amide lipid, a mixture of alkyl ether sulfate

surfactants, a cationic polymer, and the other requisite components of the composition in the specific amounts as recited by the instant claims.

'548 and Hoshowski et al are relied upon as set forth above.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to formulate the composition as taught by '766 at a pH as recited by the instant claims, with a reasonable expectation of success, because Hoshowski, teach formulating similar shampoo compositions at a pH as which is the same as recited by the instant claims.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use a mixture of alkyl ether sulfate surfactants in the composition taught by '766, with a reasonable expectation of success, because '548 teaches the use of a mixture of alkyl ether sulfate surfactants in a similar shampoo composition and further, '766 teaches the use of alkyl ether sulfate surfactants in general.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use a cationic polymer in the composition taught by '766, with a reasonable expectation of success, because '548 teaches that cationic polymers serve as conditioning agents for hair in a similar shampoo composition and further, '766 teaches the use of various optional ingredients which would encompass cationic polymers.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to formulate a composition having the specific pH containing an

amphiphatic amide lipid, a mixture of alkyl ether sulfate surfactants, and the other requisite components of the composition in the specific amounts as recited by the instant claims, with a reasonable expectation of success and similar results with respect to other disclosed components, because the broad teachings of '766 in combination with '548 and Hoshowski et al suggest a composition having the specific pH containing an amphiphatic amide lipid, a mixture of alkyl ether sulfate surfactants, and the other requisite components of the composition in the specific amounts as recited by the instant claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4, and 6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21of copending

Application No. 10/743836 and claims 1-10 of 11/245071. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-21 of copending Application No. 10/743836 and claims 1-10 of 11/245071.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to formulate a composition containing an amphiphatic amide lipid, a mixture of alkyl ether sulfate surfactants, and the other requisite components of the composition in the specific amounts as recited by the instant claims, with a reasonable expectation of success and similar results with respect to other disclosed components, because claims 1-21 of copending Application No. 10/743836 and claims 1-10 of 11/245071 of suggest a composition containing an amphiphatic amide lipid, a mixture of alkyl ether sulfate surfactants, and the other requisite components of the composition in the specific amounts as recited by the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

With respect to WO97/35548 and '766, Applicant once again states that none of these references discloses or suggest a composition containing ethylene oxide ether sulfates having at least 70% by weight of sulfates where a=0-2, nor quantify the amounts as claimed of sulfate where a=0, a=1, and a=2. Additionally, Applicant states that '548 and '766 fail to disclose or suggest the claim limitation of a pH of 1 to 5 at 25 degrees Celsius when diluted to 20 times its weight with water and that Hoshowski et al, while teaching that the final pH of the composition is from 2.5 to less than 7, does not

teach a pH of from 1 to 5 when diluted to 20 times its weight with water nor would one of ordinary skill in the art be motivated to formulate the compositions taught by '548 or '766 at the pH range disclosed by Hoshowski. Further, Applicant states that the pH of the compositions taught by Hoshowski et al are formulated at a pH of from 2.5 to 7 in order to keep the amidoamine component in a cationic state and the amidoamine is not disclosed as a component of either '548 or '766, thus one skilled in the art would not be motivated to formulate the compositions taught by '548 or '766 at such a pH.

In response, note that, the Examiner maintains that the broad teachings of '548 or '766 in combination with '548 suggest compositions containing the same distribution of sulfate surfactants as recited by the instant claims. While Applicant states that a broad genus does not render obvious a specific species and there is nothing in the cited reference to suggest modification of the distribution of ethylene oxide units to be as claimed, '548 teaches that alkyl sulfates such as ammonium lauryl sulfate, etc., are preferably used in the composition which simply correspond to a sulfate surfactant in which a=0 as recited by the instant claims (See page 9, lines 1-20 of '548). Additionally, '548 teaches that mixtures of alkyl ethoxylate sulfate surfactants are particularly preferred (See page 6, lines 10-25 of '548) which would clearly suggest to one of ordinary skill in the art the desirability of using mixtures of alkyl ethoxylated sulfate surfactants. Thus, the Examiner asserts that '548 suggest using mixtures of alkyl sulfates and alkyl ethoxylated sulfate surfactants as recited by the instant claims. Note that, the Examiner asserts that Applicant has not provided data which is commensurate in scope with the instant claims (see below for discussion) showing the

criticality with respect to the specific distribution of sulfate surfactants as recited by the instant claims.

Additionally, the Examiner maintains that Hoshowski et al is analogous prior art relative to '548 or '766 and that one of ordinary skill in the art clearly would look to the teachings of Hoshowski et al to cure the deficiencies of '548 or '766. The Examiner maintains that Hoshowski et al teach that the overall pH of the composition is from 2.5 to 7 and that one skilled in the art formulating a similar shampoo composition, such as those taught by '548 or '766 would also be motivated to formulate a composition having an overall pH of from 2.5 to 7. Further, irrespective of Hoshowski's teaching of a particular pH for allowing a cationic amidoamine, Hoshowski et al teach that a composition having a pH of above about 2.5 up to a pH of about 11 is a clear composition that generates a stable and copious foam volume. However, Hoshowski et al teach that in practice, a hair shampoo composition is adjusted to a pH of less than 7 to provide a composition that is non-irritating and non-damaging to the hair, skin and eyes of the consumer (See column 14, lines 1-10 of Hoshowski et al). Thus, the Examiner asserts that clearly '548 or '766, both in combination with Hoshowski et al, would suggest formulating the compositions of '548 and '766 at a range of from about 2.5 to 7 which would overlap with the pH as recited by the instant claims.

Further, the Examiner maintains that compositions as taught by '548 and '766, when formulated at a pH as directed and suggested by Hoshowski et al, would have a pH which overlaps with the pH recited by the instant claims when diluted to 20 times its weight with water. For example, a composition as taught by '548 or '766 formulated at a

pH of 3.5 or 3 as directed by Hoshowski would have a pH which is the same or similar to the pH of the compositions appearing in Examples 1-3 on page 29 of the instant specification. These compositions would then be expected to have a pH of from 1 to 5 at 25 degrees Celsius when diluted to 20 times its weight with water as recited by the instant claims. Thus, the Examiner maintains that the teachings of '548 or '766, both in combination with Hoshowski, would suggest compositions having the same pH at 25 degrees Celsius when diluted to 20 times its weight with water as recited by the instant claims.

Additionally, Applicant once again states that data has been presented in the instant specification which shows the unexpected and superior properties of the claimed invention in comparison to compositions falling outside the scope of the instant claims. Specifically, Applicant states that the composition as recited by the instant claims demonstrates unexpected improvement in foaming speed in comparison to compositions falling outside the scope of the instant claims. In response, note that, the Examiner once again maintains that the data presented in not sufficient to place the instant claims in condition for allowance. The data presented is not commensurate in scope with the composition as recited by the instant claims. The data shows results with respect to only one specific amphiphatic amine lipid at one specific amount while claim 1 is open to any amount of amphiphatic amine lipid which is not commensurate in scope with the instant claims. Additionally, for example, claim 1 recites a range of 5 to 30% by weight of sulfate surfactants and any cationic polymer in any amount while the data shows results with respect to sulfates at only 10% by weight and two specific

cationic polymers in two specific amounts, which is not commensurate in scope with the instant claims. Note that, while the Examiner does recognize that instant claim 1 is limited to one specific amphipathic amide lipid, the instant claims, as noted above, are still open to any amount of lipid, any cationic polymer in any amount, and a pH of from 1 to 5 and the Examiner maintains that the data presented does not provide unexpected and superior results across such broad ranges.

With respect to the provisional obviousness type double patenting rejection as set forth above, Applicant states that neither 10/743836 or 11/245071 claims an amphipathic lipid or mixture of alkyl ether sulfates as claimed. In response, note that, the Examiner maintains that each of 10/743836 and 11/245071 claim the use of amphipathic lipids and alkyl ether sulfates as recited by the instant claims. Specifically, for example, claim 10 of 10/743836 claims the exact same amphipathic lipid as recited by the instant claims. Thus, the Examiner maintains that the claims of 10/743836 or 11/245071 are sufficient to suggest the composition as recited by the instant claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory R. Del Cotto whose telephone number is (571) 272-1312. The examiner can normally be reached on Mon. thru Fri. from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on (571) 272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gregory R. Del Cotto
Primary Examiner
Art Unit 1796

GRD

January 20, 2008